a barrier layer that inhibits the formation of adhesions with tissue and organs, the barrier layer being configured to inhibit the formation of adhesions between at least a portion of the layer of repair fabric and adjacent tissue and organs.

REMARKS

Applicants respectfully request reconsideration in view of the foregoing amendments and the following remarks. Claims 1-59 are pending; claims 8-13 and 22-28 have been withdrawn from consideration. Claim 54 has been amended. No new matter has been added.

Restriction Requirement

Applicants respectfully request reconsideration of the restriction requirement of November 8, 2001 between claims 1-21 and 29-59 in Group I and claims 22-28 in Group II. The restriction is based on distinct inventions between the product and the process of using the product. In particular, the Examiner has indicated that the claimed product can be used in a materially different process of use, such as the repair of a blood vessel wall.

As discussed in Applicants' response of February 6, 2002, the product claims are directed to an implantable prosthesis for repairing a tissue or muscle wall defect, while the process claims are directed to a method of repairing a tissue or muscle wall defect using a prosthesis comparable to that defined by some of the product claims. Applicants believe that a search of the product claims would encompass a search of the process claims and, therefore, would not place a serious burden on the Examiner. Thus, Applicants request that the restriction requirement be withdrawn and claims 22-28 also be examined in this application.

Claim Rejections Under 35 U.S.C § 102(b)

Claims 1-4, 14-17, 20, 21, 37-39 and 42-44

Claims 1-4, 14-17, 20, 21, 37-39 and 42-44 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Eldridge et al. (WO 98/49967). Applicants respectfully traverse these rejections.

Independent claim 1 is directed to an implantable prosthesis for repairing a tissue or muscle wall defect. The prosthesis includes, *inter alia*, a peripheral barrier that inhibits the formation of adhesions with tissue and organs. The peripheral barrier extends about at least a portion of the outer peripheral edge of a layer of repair fabric (that is susceptible to the formation

of adhesions) to inhibit the formation of adhesions between the peripheral edge and adjacent tissue and organs.

The Examiner contends that Eldridge discloses a prosthesis with a peripheral barrier formed by melting a middle layer of repair fabric to a PTFE barrier layer. Applicants respectfully disagree.

Eldridge discloses a composite prosthesis that includes a first tissue infiltratable sheet, an adhesion resistant barrier sheet, and a second tissue infiltratable sheet that is attached to the first tissue infiltratable sheet and fused to the barrier sheet. In this regard, Eldridge indicates that at least a surface portion of the second sheet melts during a lamination process and flows into the microporous structure of the barrier sheet to form a mechanical fixation between the materials. (Eldridge page 2, lines 1-5). However, fusing the barrier sheet to the second sheet does not result in a peripheral barrier that inhibits the formation of adhesions to the outer peripheral edge of an otherwise tissue infiltratable layer. Initially, it is unclear if fusing the second sheet to the barrier sheet of the Eldridge prosthesis even renders any portion of the second sheet resistant to the formation of adhesions. To the extent that the surface of the second sheet is melted such that it would be rendered adhesion resistant, the inner portion of the melted surface would share the same characteristics as the outer periphery of the surface. Thus, the entire surface would be either adhesion resistant or tissue infiltratable. The inner portion of the surface would not be tissue infiltratable while its outer periphery is adhesion resistant. Additionally, any portion of the second sheet that is melted would overlie a corresponding surface portion of the first sheet and would not extend about any portion of the outer peripheral edge of the first sheet to form a peripheral barrier.

In view of the forgoing, independent claim 1 patentably distinguishes over Eldridge, such that the rejection under § 102(b) should be withdrawn. Claims 2-4, 14-17, 20 and 21 depend from claim 1 and are patentable for at least the same reasons.

Independent claim 37 is directed to an implantable prosthesis for repairing a tissue or muscle wall defect. The prosthesis includes, *inter alia*, a layer of repair fabric that is susceptible to the formation of adhesions and includes an outer margin with an outer peripheral edge, wherein the outer margin has been melted and resolidified to render the outer peripheral edge resistant to the formation of adhesions.

In Eldridge, as discussed above, to the extent that the second sheet is melted such that it would be rendered adhesion resistant, both the inner portion and the outer peripheral edge of the

melted surface would be adhesion resistant and not susceptible to the formation of adhesions. The inner portion of the sheet would not be tissue infiltratable while its outer peripheral edge is adhesion resistant.

In view of the forgoing, independent claim 37 patentably distinguishes over Eldridge, such that the rejection of claim 37 under § 102(b) should be withdrawn. Claims 38-39 and 42-44 depend from claim 37 and are patentable for at least the same reasons.

Claim Rejections Under 35 U.S.C § 103(a)

Claims 18, 19, 45-48 and 53

Claims 18, 19, 45-48 and 53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Eldridge et al. in view of Sharber et al. (US 6,075,180). Applicants respectfully traverse these rejections.

Initially, claims 18-19 and claim 45 respectively depend from independent claims 1 and 37 and are patentable for at least the same reasons set forth above.

Independent claim 46 is directed to an implantable prosthesis for repairing a tissue or muscle wall defect. The prosthesis includes, *inter alia*, a layer of repair fabric and a barrier layer that is joined to a surface portion of the layer of repair fabric with a plurality of connecting stitches formed from PTFE to inhibit the formation of adhesions thereto.

In the Office Action, the Examiner recognizes that Eldridge fails to disclose the use of PTFE stitches. The Examiner, however, contends that Sharber teaches the use of PTFE for suture material due to its low reactivity in the body. The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the Sharber PTFE sutures for the Eldridge sutures to provide a material unlikely to react negatively in the body. Applicants respectfully disagree.

The references do not provide the alleged motivation for combining Eldridge and Sharber as suggested by the Examiner. Additionally, one of ordinary skill in the art would have been directed away from the alleged combination. Further, even if combined as suggested by the Examiner, the claims patentably distinguish over the alleged combination.

As discussed above, Eldridge discloses a prosthesis having a laminate composite construction. More particularly, two layers of mesh fabric, such as polypropylene mesh, are joined together and a barrier sheet is fused to the surface of one of the mesh layers. Eldridge indicates any of a number of methods may be used to join the mesh layers, including knitting or

stitching. Applicants assume that the Examiner means stitches joining the mesh layers when referring to the Eldridge sutures.

Sharber discloses a carvable implant material comprised of multiple layers of porous PTFE that are laminated together with an adhesive which increases the stiffness and therefore the carvability of the implant. In the background of the invention, Sharber indicates that PTFE has a long history of use as an implantable material because it is one of the least reactive materials known. One known application for PTFE identified by Sharber is sutures.

One of ordinary skill in the art would not have been motivated to employ PTFE sutures for the connecting stitches used in the Eldridge composite prosthesis based on Sharber. The references do not suggest that the connecting stitches used in the Eldridge prosthesis are any more likely to react negatively in the body than PTFE sutures. Additionally, Sharber does not teach or suggest using PTFE sutures to join layers of mesh fabric together. In fact, Sharber discloses laminating layers of material together with adhesive, such that one of skill would have been led away from using connecting stitches to join layers of material together in view of Sharber. Thus, the Examiner has failed to establish a prima facie case of obviousness. Accordingly, the rejections of claims 18, 19, 45-48 and 53 under § 103 are improper and should be withdrawn.

Even when assuming, for the sake of argument only, that one of ordinary skill would have been motivated to employ PTFE sutures for the Eldridge connecting stitches, the claims patentably distinguish over the combination.

Claim 46 recites that the PTFE connecting stitches join a barrier layer to a portion of the surface of a layer of repair fabric. In contrast, Eldridge employs stitches to join the two layers of mesh fabric to one another, while the barrier layer is fused to one of the mesh layers. Thus, even were the Eldridge stitches formed from PTFE, the stitches would not be joining the barrier sheet to the mesh fabric. Consequently, claim 46 patentably distinguishes over Eldridge and Sharber, such that the rejection under § 103 should be withdrawn.

Claims 47-48 and 53 depend from claim 46 and are patentable for at least the same reasons.

Claims 49-52 and 54-59

Claims 49-52 and 54-59 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Eldridge et al. in view of Sharber et al., and in further view of Darois (US 6,258,124).

Initially, claims 49-52 depend from independent claim 46 and are patentable for at least the same reasons set forth above.

Neither Eldridge nor Sharber discloses a layer of repair fabric that includes an outer margin that is reinforced to form a bite region for securing the prosthesis along the outer margin. In the Office Action, the Examiner relies on Darois for disclosing an outer margin that is reinforced by stitches to form a bite region between the outermost stitch series and the outer peripheral edge. The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Eldridge prosthesis with PTFE stitches in view of Sharber and to also employ the concentric pattern disclosed by Darois to securely join the fabric layer to the barrier layer to prevent separation after implantation. Applicants respectfully disagree.

As discussed above, one of ordinary skill in the art would not have been motivated to employ PTFE sutures for the connecting stitches used in the Eldridge composite prosthesis based on Sharber. The references do not suggest that the connecting stitches used in the Eldridge prosthesis are any more likely to react negatively in the body than PTFE sutures. Additionally, Sharber does not teach or suggest using PTFE sutures to join layers of mesh fabric together. In fact, Sharber discloses laminating layers of material together with adhesive, such that one of skill would have been led away from using connecting stitches to join layers of material together in view of Sharber.

Additionally, one of ordinary skill in the art would not have been motivated to employ any particular stitch pattern of Darois with the Eldridge prosthesis. Darois discloses a composite prosthetic repair fabric that employs stitches 38 to join a layer of tissue infiltratable fabric 22 and an adhesion resistant barrier 24 together. In contrast, as discussed above, the barrier sheet in the Eldridge prosthesis is heat fused to the mesh fabric. Therefore, one of ordinary skill in the art would not have been motivated to employ the Darois stitch pattern to join the barrier sheet and mesh fabric in the Eldridge device when they are already fused to each other to prevent separation after implantation.

In view of the foregoing, the Examiner has failed to establish a prima facie case of obviousness. Accordingly, the rejections of claims 49-52 and 54-59 under §103 are improper and should be withdrawn.

Notwithstanding the foregoing, Applicants have amended independent claim 54 to clearly distinguish Darois. Claim 54 is directed to an implantable prosthesis for repairing a tissue or muscle wall defect. The implantable prosthesis comprises, *inter alia*, a layer of repair fabric that is susceptible to the formation of adhesions with tissue and organs, the layer of repair fabric including an outer margin with an outer peripheral edge. As amended, the outer peripheral edge is adapted to inhibit the formation of adhesions thereto, and the outer margin is reinforced to form a bite region that is spaced inward of the outer peripheral edge for securing the prosthesis along the outer margin.

As indicated above, Darois discloses a composite prosthetic repair fabric including a layer of tissue infiltratable fabric 22 that is joined to an adhesion resistant barrier 24 with a series stitches 38 that follow the contour of the peripheral edge of the prosthesis. Darois, however, fails to teach or suggest a layer of repair fabric that is susceptible to the formation of adhesions and includes an outer margin with an outer peripheral edge that is adapted to inhibit the formation of adhesions thereto. In Darois, the outer peripheral edge of the tissue infiltratable fabric is susceptible to the formation of adhesions. Eldridge and Sharber fail to cure the deficiency of Darois. Accordingly, claim 54 patentably distinguishes over Darois, Eldridge and Sharber.

Claims 55-59 depend from claim 54 and are patentable for at least the same reasons.

Claims 5-7, 29-36 and 40-41

Claims 5-7, 29-36 and 40-41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Eldridge et al. in view of Pajotin et al. (US 6,368,541).

Initially, claims 5-7 and 40-41 respectively depend from independent claims 1 and 37 and are patentable for at least the same reasons set forth above.

Independent claim 29 is directed to an implantable prosthesis for repairing a tissue or muscle wall defect. The prosthesis comprises, *inter alia*, a layer of repair fabric that is susceptible to the formation of adhesions and a barrier layer that inhibits the formation of adhesions between at least a portion of a surface of the layer of repair fabric and adjacent tissue and organs. The layer of repair fabric includes an inner body and outer margin extending from

the inner body, wherein the outer margin includes an outer peripheral edge that has a thickness that is less than the thickness of the inner body.

Eldridge does not disclose a layer of repair fabric having an outer peripheral edge with a thickness that is less than the thickness of the inner body of the repair fabric. In the Office Action, the Examiner contends that Pajotin teaches an implantable prosthesis that has a tapered peripheral edge to assist implantation. The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Eldridge prosthesis to include a tapered edge in view of Pajotin to assist implantation of the prosthesis into the body. Applicants respectfully disagree.

Pajotin is directed to a preformed prosthetic mesh having a curved, three-dimensional shape particularly suited for repairs in the inguinofemoral region. The prosthesis includes several distinctly shaped portions including a spherical cap 1 and a conical portion 4 that tapers away from the spherical cap to an outer tip 5. Pajotin, however, does not disclose a layer of repair fabric in which the thickness of the outer peripheral edge is less than the thickness of the inner body of the repair fabric. Rather, the device is formed from a flat piece of mesh which is heated between mating templates to set the material in a desired contoured shape. (Pajotin Figure 3; col. 2, lines 22-28; and col. 3, lines 1-12). This results in the mesh being configured with a generally concave inner surface and convex outer surface. Figure 2, which the Examiner appears to rely upon for disclosing a repair fabric having varying thickness, merely provides a prospective view of this three-dimensional curved prosthetic. It does not disclose a layer of repair fabric having varying thicknesses.

Pajotin discloses that it is desirable for the margins of the mesh to be more rigid than the remainder of the mesh so that the prosthetic mesh may resume its approximate original curved shape after being temporarily deformed. Pajotin explains that the margins of the mesh may be made more rigid by fusing the material marginally. Pajotin also indicates that the margins are preferably smooth to keep the mesh from catching as it is being positioned. (Pajotin col. 1, lines 45-61). Pajotin, however, does not teach or suggest that the thickness of the margin is less than the thickness of the inner portion of the device.

Notwithstanding the foregoing, Applicants acknowledge that C.R. Bard has been manufacturing and selling a commercialized version of the Pajotin device under the trade name 3DMax™ (enclosed is a copy of the webpage www.davol.com/max.htm describing this product), which does employ an outer peripheral margin that is thinner than the inner portion of the curved

mesh. As explained in Pajotin, the fused margin provides rigidity that allows the mesh to regain its curved shape after being temporarily deformed. The fused margin is also smoother than the rest of the prosthetic.

One of ordinary skill in the art would not have been motivated to modify Eldridge with a fused outer peripheral edge in view of the teachings of Pajotin and/or the 3DMax device. As explained above, Pajotin discloses and the 3DMax device employs a fused outer margin that is more rigid than the remainder of the prosthetic mesh so that the prosthesis may regain its original curved shape after a temporary defamation. In contrast, Eldridge discloses a flat, flexible prosthesis that may be manipulated by a surgeon for any suitable repair procedure. Eldridge does not have a preformed curved shape that requires preservation, such that one of ordinary skill in the art would not have been motivated to form a rigid margin on the Eldridge prosthesis based on the teachings of Pajotin. Additionally, although Pajotin suggests that a smooth edge may keep the prosthetic mesh from catching as it is being positioned, one of ordinary skill in the art would not have been motivated to even provide such a smooth edge on the Eldridge device. In this regard, Eldridge indicates that the composite prosthesis may be cut by a surgeon at the time of surgical placement, presumably to allow the surgeon to custom shape the prosthesis for the particular repair procedure (Eldridge page 4, lines 17-18). Thus, one of ordinary skill would not have been motivated to fuse the outer margin of the Eldridge prosthesis since a surgeon would be removing some or all of the fused outer margin when cutting the prosthesis into a desired shape at the time of surgical placement.

In view of the foregoing, the Examiner has failed to establish a prima facie case of obviousness. Accordingly, the rejection of independent claim 29 under § 103 is improper and should be withdrawn. Claims 30-36 depend from claim 29 and are patentable for at least the same reasons.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicants' attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee

occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
Cherok et al, Applicants

James M. Hanifin, Jr., Reg. No. 39,213
WOLF, GREENFIELD & SACKS, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210
Tel. (617) 720-3500

Date: August 16, 2002
X 08/16/02

MARKED-UP CLAIMS

54. (Amended) An implantable prosthesis for repairing a tissue or muscle wall defect, the implantable prosthesis comprising:

a layer of repair fabric that is susceptible to the formation of adhesions with tissue and organs, the layer of repair fabric including an outer margin with an outer peripheral edge, the outer peripheral edge being adapted to inhibit the formation of adhesions thereto, the outer margin being reinforced to form a bite region that is spaced inward of the outer peripheral edge for securing the prosthesis along the outer margin; and

a barrier layer that inhibits the formation of adhesions with tissue and organs, the barrier layer being configured to inhibit the formation of adhesions between at least a portion of the [first surface] layer of repair fabric and adjacent tissue and organs.

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Davol Inc.
1100 Sockanossett Crossroad.
PO Box 8500
Cranston, RI 02920
Phone: 401-463-7000
Fax: 401-946-5379
Email: info@davol.com

Bard® 3DMax™ Mesh

Three-dimensional, anatomically-formed mesh for use in laparoscopic hernia repair

The **Bard 3DMax** mesh is a three-dimensional, anatomically formed prosthesis for use in laparoscopic hernia repair. The **Bard 3DMax** mesh has been designed based on careful and precise anatomical research of the inguinal canal. The result is a truly unique prosthesis for laparoscopic hernia surgery.

The **Bard 3DMax** product is constructed of **Bard** mesh, knitted polypropylene monofilament. The knit construction allows the mesh to be stretched in both directions in order to accommodate and reinforce tissue defects. The use of **Bard** mesh allows a prompt fibroblastic response through the interstices of the mesh, forming a strong fibrous wall.[2]

The **Bard 3DMax** mesh was developed by Dr. Philippe Pajotin, a prominent laparoscopic surgeon. After years of performing a transabdominal preperitoneal (TAPP) repair, Dr. Pajotin came to the realization that a flat sheet of mesh may not be the ideal configuration for a laparoscopic repair. After all, the inguinal anatomy was anything but the two-dimensional image seen on the monitor. So, after careful cadaver research and molding, Dr. Pajotin developed what he believed to be the ideal prosthetic–one that was anatomically formed and shaped to the inguinal anatomy.[1]

The **Bard 3DMax** mesh offers significant advantages over current laparoscopic mesh alternatives:

Anatomically formed - The **Bard 3DMax** mesh is perfectly suited to the inguinal anatomy based on cadaver research and molding. It is a three-dimensional, anatomically shaped mesh for use in laparoscopic hernia repair.

Comes in left & right orientations - Due to its precise anatomical form, the **Bard 3DMax** mesh is offered in a left and right orientation. This allows for precise and specific mesh positioning for any inguinal hernia.

Reinforced edge - A reinforced edge helps to maintain the curved, three-dimensional shape of the **Bard 3DMax** mesh. Additionally, this edge allows for easier mesh positioning and overall fixation.

3DMax Home Page | Positioning | Introduction
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Note: This site is designed specifically for qualified healthcare professionals.

[1]Pajotin, Ph. "Laparoscopic Groin Hernia Repair Using a Curved Prosthesis Without Fixation". *Le journal de Coelio-Chirurgie* – No. 28, p.64 –December 1998

[2]Lichtenstein, I.L., Hernia Repair without Disability, 2nd Edition, St. Louis, 1986, Ishiyaker Euro America, Inc.

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